PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 75.154/BE	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/HU 02/00082	International filing date *(day/month/year)* 13.08.2002	Priority date *(day/month/year)* 13.08.2002
International Patent Classification (IPC) or both national classification and IPC A23K1/16		
Applicant HIDVEGI, Máté et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.02.2004	10.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Merkl, B Telephone No. +49 89 2399-2138

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/HU 02/00082

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-23 as originally filed

Claims, Numbers

1-15 received on 25.08.2004 with letter of 19.08.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 13-15

   because:

   ☒ the said international application, or the said claims Nos. 13-15 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,4-15
	No:	Claims	2,3
Inventive step (IS)	Yes:	Claims	1, 5-15
	No:	Claims	2-4
Industrial applicability (IA)	Yes:	Claims	1-15 (see item III)
	No:	Claims	

2. Citations and explanations

   see separate sheet

Item III:

For the assessment of the present claims 13-15 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Claims 13-15 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT as the yield enhancing is is directly linked to the prevention or treatments of diseases, e.g. infections. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Item V:

1. D1: DATABASE WPI Section Ch, Week 198212 Derwent Publications Ltd., London, GB; Class C03, AN 1982-22857E XP002237212 & JP 57 026586 A (MURATA T) 12 February 1982 (1982-02-12)
   D2: WO 97/28699 A (MENA ANNALISA ;GIUFFRE ISLER LAURA (CH)) 14 August 1997 (1997-08-14)
   D3: WO 99/08694 A (RASO ERZSEBET ;SZENDE BELA (HU); HIDVEGI MATE (HU); LAPIS KAROLY () 25 February 1999 (1999-02-25)
   D4: M. HIDVEGI ET AL.: "Effect of MSC on the immune response of mice" IMMUNOPHARMACOLOGY., vol. 41, no. 3, 1999, pages 183-186, XP002237211 ELSEVIER SCIENCE PUBLISHERS BV., XX ISSN: 0162-3109
   D5: DATABASE WPI Section Ch, Week 200147 Derwent Publications Ltd., London, GB; Class D13, AN 2001-435959 XP002237213 & JP 2001 120203 A (OTO CORP YG) 8 May 2001 (2001-05-08)

2. D1 discloses a composition comprising among others as ingredient fermented wheat germ compounds. D3 discloses a composition comprising wheat germ compounds fermented by Saccharomyces cerevisiae which has an immunostimulatory effect in mammals.
   Claims 2-4 are directed to compositions comprising wheat germ extract in a

specified amount (claims 2 and 3) and which additionally (in claim 4) is derived from a fermeted liquid and biomass obtainable by fermenting wheat germ with Saccharomyces cerevisiae. As in claims 2 and 3 the kind of extract (concentration, extraction medium, ingredients) is not defined the amount of active ingredients in said extract is unclear. Therefore the ranges defined in said claims (0.001-10; 0.001-50% by weight) are not suitable to give a precise definition of the active ingredients in the compositions. Which means that the scope of said claims is not well defined. Therefore the feature consisting of the definition of "wheat germ extract in an amount of ...." is is vague and therefore not suitable to distinguish the subject-matter claimed in claims 2 and 3 from the composition disclosed in D1 which also comprises a fermented wheat germ extract. Therefore claims 2 and 3 do not meet the requirements of novelty (Art. 33(2) PCT).

The only difference of the subject-matter defined in claim 4 with respect to D1 is that in D1 the fermenting agent is not disclosed. However, D3 discloses that wheat germ fermented by Saccharomyces cerevisiae has an immunostimulatory effect. Therefore no inventive step was necessary to use said fermenting agent to reduce diseases in animals (D1, abstract, line 3) or to increase the power of resistance of animals against diseases (pending application, page 1, lines 16-17). Therefore claim 4 does not meet the requirements of inventive step (Art. 33(3) PCT).

The remaining claims which are directed to weight gain and efficiency of feed conversion or the treatment of specific diseases are regarded to be novel and inventive as the documents cited in the search report do not disclose said features nor do the give any hint to use fermented wheat germ extract for said purposes.

Amended claims

1. Use of fermented wheat germ extract for the manufacture of fodders, nutriments or premixes for enhancing weight gain and efficiency of feed conversion in animals.

2. Fodder or nutriment containing as fodder additive fermented wheat germ extract in an amount of 0,001-10% by weight.

3. Fodder- or nutriment premix containing as fodder additive fermented wheat germ extract in an amount of 0,001-50% by weight.

4. Fodder, nutriment or premix according to Claim 2 or 3 wherein the fermented wheat germ extract derived from a fermented liquid and biomass obtainable by fermenting wheat germ with Saccharomyces cerevisiae in an aqueous medium.

5. A method of enhancing weight gain and efficiency of feed conversion in farm animals characterized in that fermented wheat germ extract is given as weight gain and feed efficiency enhancing additive to the fodder of the animals and the animals are fed with the fodder obtained in this manner.

6. The method according to Claim 5 characterized in that said weight gain and feed efficiency enhancing additive is employed in an amount of 0,1-6 g/kg fodder, preferably in an amount of 0,3-3 g/kg fodder.

7. The method according to Claim 5 or 6 wherein the farm animal is cattle, horse, rabbit, pigglet, fattening pig, broiler chicken, egg-laying hen, turkey, goose or duck.

8. Use of fermented wheat germ extract for the manufacture of a preparation for enhancing weight gain and feed efficiency of farm animals.

9. Use of fermented wheat germ extract for the manufacture of a preparation for preventing and/or treating animal's Mycoplasma infections.

10. Use of fermented wheat germ extract for the manufacture of a preparation for preventing and/or treating animal's infectious inflammations, particularly pneumonia caused by M. hyopneumoniae.

11. Use of fermented wheat germ extract for the manufacture of a preparation for preventing and/or treating coccidiosis infection of poultry.

12. Use of fermented wheat germ extract for the manufacture of a preparation for increasing antibody titer of vaccinated poultry.

13. Use of fermented wheat germ extract for preventing and/or reducing Mycoplasma gallisepticum or Mycoplasma synoviae infection and/or coccidiosis infection in poultry.

14. Use of fermented wheat germ extract for preventing pneumonia caused by M. hyopneumoniae.

15. The use according to Claim 1 or 8 or any one of Claims 11 to 13 wherein the fermented wheat germ extract is employed by mixing said extract to the usual fodder in an amount of 0,1 - 6 g/kg fodder.